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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,098	06/15/2005	Mitchell Skop	1114-5 PCT/US	7129

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EXAMINER	
TATE, CHRISTOPHER ROBIN	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
07/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,098	SKOP ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0905*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 are presented for examination on the merits.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cinco et al. (J. Food Sci, 1985), or Iguti et al. (J. Agric. Food Chem., 1991), or Ho et al. (J. Food Biochem., 1993), or Gibbs et al. (Food Res. Intl., 1998), or Pick et al. (Prep. Biochem., 1979), or Marshall et al. (J. Biol. Chem., 1975).

The claims are drawn to a purified amylase inhibitor obtained from white kidney beans.

Each of the cited references expressly teaches a purified amylase inhibitor obtained from white kidney beans - via a series of purification steps discussed therein (please note that some of the cited references even refer to their purified amylase inhibitor as phaseolamin which - as readily admitted by Applicants, is the same amylase inhibitor as instantly claimed (see, e.g., page 3, lines 21-22, of the instant specification) - see entire documents, especially the *Materials and*

Methods section). Consequently, the claimed purified amylase inhibitor appears to be anticipated by each of the cited references.

In the alternative, even if the claimed purified amylase inhibitor is not identical to one or more of the referenced purified amylase inhibitors with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced purified amylase inhibitors is/are likely to inherently possess the same characteristics of the claimed purified amylase inhibitor particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed purified amylase inhibitor would have been obvious to those of ordinary skill in the art within the meaning of USC 103. If necessary, the adjustment of particular conventional working conditions (e.g., further drying/lyophilizing the purified amylase inhibitor(s) so as to enhance shelf-stability/storage, etc) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by each of the cited references, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the USC 102/103 rejections above, please note that in product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cinco et al. (J. Food Sci, 1985), or Iguti et al. (J. Agric. Food Chem., 1991), or Ho et al. (J. Food Biochem., 1993), or Gibbs et al. (Food Res. Intl., 1998), or Pick et al. (Prep. Biochem., 1979), or Marshall et al. (J. Biol. Chem., 1975), in view of Layer et al. (Gastroenterol., 1985) and Woeber (DE 2628757 - DWPI and CAPLUS Abstracts).

The primary references are relied upon for the reasons set forth above. These references do not necessarily expressly teach that their purified amylase inhibitor can be used to induce weight loss or to treat diabetes (via the instantly claimed functional effect - i.e., via improving post-prandial glucose tolerance).

Layer et al. beneficially teach that partially purified amylase inhibitors from white kidney beans (vs. crude preparations thereof) perform better at slowing carbohydrate digestion and absorption as well as increasing passage of malabsorbed carbohydrates into the colon and, thus, may be beneficial for obese subjects and subjects having diabetes mellitus (see, e.g., page 895 - top of second column, and page 1901 - under the heading *Digestion of Starch*).

Woeber beneficially discloses that a purified amylase inhibitor from *Phaseolus vulgaris* (kidney bean), in a lyophilized form, can be used in the therapy of obesity and diabetes (see DWPI and CAPLUS abstracts).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat a subject suffering from obesity (via inducing weight loss) or a subject suffering from diabetes by administering a purified amylase inhibitor as taught by each of the primary references, based upon the beneficial teachings provided the secondary references with respect to the well known ability of such amylase inhibitors to treat these conditions (please also note that administering one of the reference purified amylase inhibitors to a diabetic subject such as one having diabetes mellitus would intrinsically provide the instantly claimed underlying effect - i.e., would intrinsically improve post-prandial glucose tolerance therein). If necessary, the adjustment of particular conventional working conditions (e.g., further drying/lyophilizing the purified amylase inhibitor(s) so as to enhance shelf-stability/storage, etc) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher R. Tate
Primary Examiner
Art Unit 1655